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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/710,423	07/09/2004	Richard Heller	1372.32.UTLCPDV2	5054
21901	7590	08/17/2006	EXAMINER	
SMITH HOPEN, PA 180 PINE AVENUE NORTH OLDSMAR, FL 34677			HUH, BENJAMIN	
			ART UNIT	PAPER NUMBER
			3767	

DATE MAILED: 08/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/710,423	Applicant(s) HELLER ET AL.	
	Examiner Benjamin Huh	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 recites the limitation "outer electrode" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Objections

Claims 10-11 are objected to because of the following informalities: claim 11 is dependent upon itself and claim 10 is dependent upon claim 11 which is dependent upon itself. Appropriate correction is required.

Claims 1 & 12 are objected to because of the following informalities: In examining the claims, the term "discrete electrodes" is found to be a broad and vague term, the applicant is requested to clarify, it is noted that in previous application 09/696350 in a office action mailed 1/21/04 a request for clarification was made in which a claim amendment was requested for the circuit communication to be deemed a "independent circuit communication". Appropriate correction is required.

Claim 2 is objected to because of the following informalities: In examining the claims, the term "higher" is seemed to be broad and vague and can be defined in multiple ways, if the applicant means for the second field to be further defined in

strength or location, the applicant is requested to clarify, currently the claim is being examined with respect to location. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 8, & 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Weaver (US Patent No. 5389069). The Weaver reference discloses a device for manipulating a molecule in vivo relative to a target tissue in figure 5 comprising an elongated member 148 comprising a generally cylindrical nonconductive core post and at least two discrete electrodes (152,154); the least two discrete electrodes being circumferential rings disposed about the core and in axially spaced relation along the elongated member, each electrode being in circuit communication with a respective portion of a source of electrical energy, the discrete electrodes being configured to establish a first electromagnetic field in vivo between selected electrodes sufficient to cause an electromigration of a molecule relative to a target tissue and a second electromagnetic field sufficient to cause a transient permeability of a cell membrane within the target tissue; and an insulating material (seen as the material between the two electrodes) interposed axially between the electrodes for achieving relative electromagnetic isolation of the electrodes, also see col. 2 lines 8-60 & col. 8 lines 5-21.

With respect to claim 2, wherein the second field is higher than the first field, see figure 5.

With respect to claim 3-4, the tip seen as the distal end of part 148 in figure 5.

With respect to claim 8, wherein the device is fully capable of having the electrodes substantially simultaneously activatable due to it's size, shape, and ability to work in the environment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 8, & 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tu et al (US Patent No. 5941845) and further in view of Goble et al (US Patent No. 5944715). The Tu reference discloses a device for manipulating a molecule in vivo relative to a target tissue comprising an elongated member comprising a generally cylindrical nonconductive core post and at least two discrete electrodes; the least two discrete electrodes being circumferential rings disposed about the core and in axially spaced relation along the elongated member, each electrode being in circuit communication with a respective portion of a source of electrical energy, the discrete electrodes being configured to establish a first electromagnetic field in vivo between

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selected electrodes sufficient to cause an electromigration of a molecule relative to a target tissue and a second electromagnetic field sufficient to cause a transient permeability of a cell membrane within the target tissue. Now even though Tu does not explicitly disclose an insulating material interposed axially between the electrodes attention is directed to Goble. The Goble reference teaches the use of an insulated material between the electrodes, see col. 3 line 64 – col. 4 line 30, col. 6 line 28 – col. 7 line 4, and abstract. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Tu with the teachings of Goble in order to provide finely defined paths and insulate between the two electrodes.

Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weaver (US Patent No. 5389069) or Tu et al (US patent No. 5941845) as applied to claim 1 and further in view of Hofmann et al (US Patent No. 6233482B1). Now even though Weaver or Tu does not explicitly disclose a plurality of members configurable to surround a periphery of a tissue or provide opposite-polarity voltages or active a plurality of electrodes in a predetermined pattern, attention is directed to Hofmann. The Hofmann reference teaches the use of a plurality of electroporation members to surround tissues, utilize opposite-polarity voltages, and activate electrodes in a predetermined pattern, see figures 2A-G, 6, & 7A-D, col. 3 line 62 – col. 8 line 36. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Weaver or Tu with the teachings of Hofmann in order

to provide electroporation therapy to a larger area as well as customizing the therapy to different tissues and operations.

Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weaver (US Patent No. 5389069) or Tu et al (US patent No. 5941845) as applied to claim 1 and further in view of Edwards et al (US Patent No. 5472441). Now even though Weaver or Tu et al does not explicitly disclose the member having a lumen and a portal, positioned along the member or adjacent a bottom tip or adjacent an electrode, for passing a substance therethrough to the target tissue attention is directed to Edwards. The Edwards et al reference teaches the use of a lumen through an electroporation member for fluid distribution for treatment of the tissues with an agent. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Tu to utilize the teachings of Edwards in order to help facilitate the distribution of the fluid treatment agents.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Huh whose telephone number is 571-272-8208. The examiner can normally be reached on M-F: 9:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BHH

BHH

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

